

What is claimed is:

1. A lyophilized topotecan liposomal composition comprising topotecan, liposomes and cryoprotectant, wherein topotecan is substantially entrapped in the liposome interior.

2. A lyophilized topotecan liposomal composition comprising topotecan, liposomes and cryoprotectant, that can be reconstituted with water to form a reconstituted composition wherein at least about 85% of the topotecan in the composition is liposome-entrapped topotecan, and wherein about 85% of the liposomes in said composition have sizes of about 0.05 to about 0.25 microns.

3. A reconstituted lyophilized topotecan liposomal composition comprising topotecan, liposomes and cryoprotectant, wherein:

about 85% of the liposomes in said composition have sizes of about 0.05 to about 0.25 microns,

at least about 85% of the topotecan in the composition is liposome-entrapped topotecan; and

the topotecan/lipid ratio is between about 0.02 to about 0.4 by weight, wherein the lipid constituents comprise cholesterol and a vesicle-forming lipid that form the liposome.

4. A lyophilized topotecan liposomal composition according to claim 1 or claim 4, comprising no more than 2% topotecan degradation products.

5. A lyophilized topotecan liposomal composition according to claim 1 or claim 4, which upon reconstitution after storage for an extended period of time produces no significant increase in the number and size of needle shaped particulate matter.

6. A lyophilized topotecan liposomal composition according to any one of claims 1 to 3, wherein said cryoprotectant comprises one or more of sucrose, trehalose and lactose.

7. A process of preparing an aqueous liposomal topotecan composition suitable for injection, wherein said composition is comprised of at least about 85% liposome-entrapped topotecan, said process comprising;

5 reconstituting the lyophilized composition according to claim 1 or claim 2 to provide said aqueous composition.

8. A process of preparing an aqueous liposomal topotecan composition suitable for injection, wherein said composition is comprised of at least about 85% liposome-entrapped topotecan, said process comprising:

10 reconstituting the lyophilized composition according to claim 1 or claim 2 to form a topotecan liposomal concentrate, and

diluting the topotecan liposomal concentrate with an aqueous medium to provide said aqueous composition having a liposome concentration suitable for intravenous injection.

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